REMARKS

This is a full and timely response to the final Office Action mailed April 21, 2005 in the present patent application. Reconsideration of the application in light of the following remarks is respectfully requested.

Status of Claims:

In a previous Restriction Requirement, claims 12-14 and 23-26 were withdrawn from consideration. In preparation for the allowance of this application, Applicant has herein cancelled the withdrawn claims.

The withdrawn claims are cancelled without prejudice or disclaimer. Applicant reserves the right to file any number of continuation or divisional applications to the cancelled claims or to any other subject matter described in the present application.

Following the cancellation of claims 12-14 and 23-26, claims 1-11 and 15-22 remain pending for further action.

Prior Art:

The sole issue raised in the outstanding final Office Action is a rejection of claims 1-11 and 15-22 as unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 6,185,452 to Schulman et al. ("Schulman" or the "Schulman reference"). For at least the following reasons, this rejection is respectfully traversed.

First, under 35 U.S.C. § 103(c), Schulman cannot be applied under § 103 as prior art against the present application.

35 U.S.C. § 103(c), in pertinent part, reads as follows:

> (c)(1) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.
> (2) For purposes of this subsection, subject matter developed by another person and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person if —
> (A) the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made;
> (B) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and
> (C) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.
> (3) For purposes of paragraph (2), the term "joint research agreement" means a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention.

In the present case, the Schulman reference issued as a patent on 6 February 2001, after the priority date of the present application, January 30, 2001. Consequently, the Schulman reference is only prior art against the present application under 35 U.S.C. § 102(e) as required by 35 U.S.C. § 103(c)(1).

The Schulman reference is assigned to the Alfred E. Mann Foundation for Scientific Research. The assignment is recorded with the U.S. Patent Office at Reel/Frame 009016/0164. The present application is assigned to Advanced Bionics Corporation. Consequently, there Schulman reference and the present application are not commonly owned.

However, under 35 U.S.C. § 103(c)(2), "subject matter developed by another person and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person if — (A) the claimed invention was made by

or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made."

On May 18, 1999, prior to the development of the claimed invention and the filing of the present application, Advanced Bionics Corporation ("Bionics") and the Alfred E. Mann Foundation for Scientific Research ("AMF") entered into a written joint research agreement within the scope of which the presently claimed invention was developed. A copy of the agreement is in the possession of the undersigned and has been reviewed for compliance with all aspects § 103(c)(2).

In pertinent part, the joint research agreement specifically identifies the Schulman patent (then a pending application) and grants an exclusive license thereto to Advanced Bionics Corporation. The agreement further obligates both the AMF and Bionics to conduct additional research in the field of battery-powered implantable devices and to share information resulting from that research.

Consequently, prior to the development of the invention claimed in the present application, there existed a "joint research agreement" in the form of a written contract or cooperative agreement entered into by Bionics and the AMF for the performance of experimental, developmental, or research work in the field of the claimed invention. This agreement was in effect at the time the subject matter of the present application was developed by one of the parties to the agreement, Advanced Bionics. 35 U.S.C. § 103(c)(2)(A).

The claimed invention of the present application was made as a result of activities undertaken within the scope of the joint research agreement as required by 35 U.S.C. § 103(c)(2)(B). Additionally, the present application has been amended herein to refer to the

joint research agreement and to name the parties thereto as required by 35 U.S.C. § 103(c)(2)(C). See the amendment above to paragraph 0001 of the specification.

Consequently, under 35 U.S.C. § 103(c), the Schulman reference cannot be applied as prior art against the present application. For at least this reason, the rejection based on Schulman must be reconsidered and withdrawn.

Additionally, the Schulman reference fails to teach or suggest all the features of the invention as presently claimed. For example, claim 1 recites:

> A method for treating a patient with chronic pain, comprising:
> identifying a patient experiencing sensations of chronic peripheral pain, wherein the chronic peripheral pain includes at least one of chronic neuropathic pain, failed back surgery syndrome, arachnoiditis, occipital neuralgia, peripherial pelvic pain, cardiac pain and back pain;
> providing at least one leadless stimulator having at least two electrodes;
> implanting the at least one leadless stimulator adjacent to at least one peripheral nerve of the patient, said peripheral nerve being responsible at least in part for the sensations of chronic pain experienced by the patient;
> providing operating power to the at least one leadless stimulator;
> using at least one external appliance to transmit stimulation parameters to the at least one leadless stimulator;
> receiving and storing the stimulation parameters within the at least one leadless stimulator;
> generating stimulation pulses within the at least one leadless stimulator in accordance with the stimulation parameters; and
> delivering the stimulation pulses from the electrodes of the at least one leadless stimulator to the at least one peripheral nerve of the patient for the purpose of reducing the sensations of chronic peripheral pain experienced by the patient;
> wherein the leadless stimulator has a size and shape suitable for placement of the electrodes adjacent to the at least one peripheral nerve.

(emphasis added).

Similarly, independent claim 15 recites:

> A method for treating a patient with chronic pain, comprising:
> identifying a patient experiencing sensations of chronic peripheral pain, wherein the chronic peripheral pain includes at least one of chronic neuropathic pain, failed back surgery syndrome, arachnoiditis, occipital neuralgia, peripherial pelvic pain, cardiac pain and back pain;
> providing at least one leadless stimulator having at least two electrodes;

providing at least one sensor;
implanting the at least one stimulator adjacent to at least one peripheral nerve of the patient, said peripheral nerve being responsible at least in part for the sensation of chronic peripheral pain experienced by the patient;
providing operating power to the at least one stimulator;
using the sensor to sense a physical condition;
determining stimulation parameters based upon the sensed condition;
generating stimulation pulses within the at least one stimulator in accordance with the stimulation parameters; and
delivering the stimulation pulses from the electrodes of the at least one stimulator to the at least one peripheral nerve of the patient for the purpose of reducing the sensations of chronic peripheral pain experienced by the patient;
wherein the stimulator has a size and shape suitable for placement of the electrodes adjacent to the at least one peripheral nerve of the patient.
(emphasis added).

In contrast, and as has been pointed out on the record previously, Schulman does not teach or suggest a method for treating chronic pain, specifically chronic pain that includes at least one of the specific disorders listed in claim 1 or 15.

The recent final Office Action acknowledges that Schulman does not "explicitly discuss a method for treating *chronic* pain." (Action of 4/21/05, p. 2) (emphasis in the original). Applicant agrees. The recent final Office Action further appears to acknowledge that Schulman does not teach or suggest the use of a leadless stimulator to treat any of the specific disorders or types of pain listed in claim 1 or 15. Nevertheless, the final Office Action draws the conclusion that the specific treatment method of claims 1 and 15 would have been obvious in view of the teachings of Schulman. This is insufficient as a matter of law.

The courts have clearly held that, where the examiner relies on a single reference under § 103, it is insufficient to merely state that it would be obvious, or a mere matter of design choice, to modify the disclosure to include the features of the claimed invention. *In re Mills*, 16 USPQ2d 1430, 1432 (Fed. Cir. 1990). "To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re*

Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)." M.P.E.P. § 2143.03. (emphasis added). Accord. M.P.E.P. § 706.02(j).

Consequently, even if Schulman were available as prior art against the present application, which Schulman is not, the Schulman reference taken alone fails to teach or suggest all the features of the claimed methods. Therefore, the Schulman reference taken alone is insufficient as a matter of law to support a rejection of the claims under § 103(a). For at least this additional reason, the rejection of the claims based on Schulman should be reconsidered and withdrawn.

Conclusion:

For the foregoing reasons, the present application is thought to be clearly in condition for allowance. Accordingly, favorable reconsideration of the application in light of these remarks is courteously solicited. If any fees are owed in connection with this paper which have not been elsewhere authorized, authorization is hereby given to charge those fees to Deposit Account 18-0013 in the name of Rader, Fishman & Grauer PLLC. If the Examiner has any comments or suggestions which could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the number listed below.

Respectfully submitted,

DATE: 15 July 2005

Steven L. Nichols
Registration No. 40,326

Steven L. Nichols, Esq.
Managing Partner, Utah Office
Rader Fishman & Grauer PLLC
River Park Corporate Center One
10653 S. River Front Parkway, Suite 150
South Jordan, Utah 84095

(801) 572-8066
(801) 572-7666 (fax)

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Rebecca R. Schow

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Patent Application of

Todd K. Whitehurst et al.

Application No. 10/057,116

Filed: January 24, 2002

For: Fully Implantable Neurostimulator for Peripheral Nerve Stimulation as a Therapy for Chronic Pain

Group Art Unit: 3762

Examiner: SCHAETZLE, Kennedy

STATEMENT

REGARDING THE EXCLUSION OF PRIOR ART UNDER 35 U.S.C. § 103(C)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

The undersigned hereby states the following for the record.

1. The sole issue raised in the outstanding final Office Action in the above-identified patent application is a rejection of claims 1-11 and 15-22 as unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 6,185,452 to Schulman et al. ("Schulman" or the "Schulman reference"). However, under 35 U.S.C. § 103(c), Schulman cannot be applied under § 103 as prior art against the present application.

2. The Schulman reference and the invention claimed in the above-identified patent application were made by or on the behalf of parties to a joint research agreement as defined by 35 U.S.C. § 103(c). The Schulman reference is assigned to the Alfred E. Mann Foundation for Scientific Research. The assignment is recorded with the U.S. Patent Office at Reel/Frame 009016/0164. The present application is assigned to Advanced Bionics Corporation. On May 18, 1999, prior to the development of the claimed invention and the filing of the present application, Advanced Bionics Corporation ("Bionics") and the Alfred E. Mann Foundation for Scientific Research ("AMF") entered into a written joint research agreement within the scope of which the presently claimed invention was developed.

3. This joint research agreement, effective May 18, 1999, was in effect before and while the invention claimed in the above-identified patent application was made, the present application being filed January 24, 2002. 35 U.S.C. § 103(c)(2)(A).

4. The invention claimed in the above-identified patent application was made as a result of activities undertaken within the scope of the join research agreement between Bionics and AMF. 35 U.S.C. § 103(c)(2)(B).

5. Consequently, under 35 U.S.C. § 103(c), the Schulman reference cannot be applied as prior art against the present application. For at least this reason, the rejection based on Schulman must be reconsidered and withdrawn.

Respectfully submitted,

DATE: 13 July 2005

Todd K. Whitehurst, MD
Vice President, Emerging Indications
On behalf of Assignee,
Advanced Bionics Corporation